IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM CORPORATION,	)	
Plaintiffs,	)	
v.	)	C.A. NO. _____
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Boehringer Ingelheim Pharmaceuticals Inc.; Boehringer Ingelheim International GmbH; and Boehringer Ingelheim Corporation, by their undersigned attorneys, for their Complaint against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc., hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendant's submissions of Abbreviated New Drug Applications ("ANDAs") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Plaintiffs' JARDIANCE® (empagliflozin) tablets, GLYXAMBI® (empagliflozin/linagliptin), SYNJARDY XR® (empagliflozin/metformin extended release), and/or TRIJARDY XR® (empagliflozin/linagliptin/metformin extended release) tablets prior to the expiration of United States Patent No. 11,090,323.

THE PARTIES

2. Plaintiff Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Rd., Ridgefield, CT 06877.

3. Plaintiff Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

4. Plaintiff Boehringer Ingelheim Corporation ("BIC") is a corporation organized and existing under the laws of Nevada, having a principal place of business at 900 Ridgebury Road, Ridgefield, CT, 06877.

5. BIPI, BII, and BIC are collectively referred to hereinafter as "Boehringer" or "Plaintiffs."

6. On information and belief, Defendant Lupin Ltd. ("Lupin") is a corporation organized and existing under the laws of India, having a principal place of business at Laxmi Towers, Bandra Kurla Complex, Bandra (East), Mumbai, India 400051.

7. On information and belief, Lupin Ltd. controls and directs a wholly owned subsidiary in the United States named Lupin Pharmaceuticals, Inc. ("Lupin Pharma"). Lupin Pharma is a Delaware corporation having a principal place of business at 111 South Calvert Street, Baltimore, Maryland 21202.

8. Lupin Ltd. and Lupin Pharma are collectively referred to hereinafter as "Lupin."

9. On information and belief, Lupin is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the state of Delaware, through its own actions and through the actions of its agents

and subsidiaries, including Lupin Pharma, from which Lupin Ltd. derives a substantial portion of its revenue.

10. On information and belief, Lupin prepared and submitted ANDA No. 212331 (the "Lupin empagliflozin ANDA") for Lupin's 10 mg and 25 mg empagliflozin tablets (the "Lupin empagliflozin ANDA Product").

11. On information and belief, Lupin prepared and submitted ANDA No. 212335 (the "Lupin empagliflozin/linagliptin ANDA") for Lupin's 10 mg/5 mg and 25 mg/5 mg empagliflozin/linagliptin tablets (the "Lupin empagliflozin/linagliptin ANDA Product").

12. On information and belief, Lupin prepared and submitted ANDA No. 213654 (the "Lupin empagliflozin/metformin extended-release ANDA") for Lupin's 5 mg/1000 mg, 10 mg/1000 mg, 12.5mg/1000 mg, and 25 mg/1000 mg extended-release tablets (the "Lupin empagliflozin/metformin extended-release ANDA Product").

13. On information and belief, Lupin prepared and submitted ANDA No. 215072 (the "Lupin empagliflozin/linagliptin/metformin extended-release ANDA") for Lupin's 5 mg/2.5 mg/1000 mg; 10 mg/5 mg/1000 mg; 12.5 mg/2.5 mg/1000 mg; 25 mg/5 mg/1000 mg empagliflozin/linagliptin/metformin extended-release tablets (the "Lupin empagliflozin/linagliptin/metformin extended-release ANDA Product").

14. The Lupin empagliflozin ANDA, Lupin empagliflozin/linagliptin ANDA, Lupin empagliflozin/metformin extended-release ANDA, and Lupin empagliflozin/metformin extended-release ANDA are collectively referred to hereinafter as the "Lupin ANDAs."

15. The Lupin empagliflozin ANDA Product, Lupin empagliflozin/linagliptin ANDA Product, Lupin empagliflozin/metformin extended-release ANDA Product, and Lupin

empagliflozin/linagliptin/metformin extended-release ANDA Product are collectively referred to hereinafter as the "Lupin ANDA Products."

16. On information and belief, following FDA approval of the Lupin ANDA, Lupin Ltd. will manufacture, supply, market, and sell the approved generic product throughout the United States at the direction, either on its own or through any number of subsidiaries and/or agents.

JURISDICTION AND VENUE

17. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

18. Venue is proper in this Court because, among other things, Lupin Pharma is incorporated in the State of Delaware and therefore "resides" in this judicial district and/or has committed acts of infringement in this district and has a regular and established place of business in this district. 28 U.S.C. § 1400(b). Lupin Ltd. is a foreign corporation not residing in any United States district and therefore may be sued in any judicial district. 28 U.S.C. § 1391(c). Moreover, Lupin has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware.

PERSONAL JURISDICTION OVER LUPIN LTD.

19. Plaintiffs reallege paragraphs 1-18 as if fully set forth herein.

20. On information and belief, Lupin Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

21. This Court has personal jurisdiction over Lupin Ltd. because, *inter alia*, Lupin Ltd., on information and belief: (1) has substantial, continuous, and systematic contacts with this State, either directly or through at least one of its wholly-owned subsidiaries or agents; (2) intends to market, sell, and/or distribute Lupin Ltd.'s infringing ANDA Products to residents of this State

upon approval of Lupin Ltd.'s ANDAs, either directly or through at least one of its wholly-owned subsidiaries or agents; and (3) enjoys substantial income from sales of its generic pharmaceutical products in this State on its own and through Lupin Pharma, which is a Delaware corporation; and (4) wholly owns Lupin Pharma, which is a Delaware corporation and is registered as a pharmacy wholesaler and controlled substances distributor/manufacturer with the Delaware Division of Professional Regulation.

22. On information and belief, Lupin Ltd. has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g.*, *Boehringer Ingelheim Pharm. Inc. v. Lupin Ltd.*, C.A. No. 18-1690-CFC (D. Del.); *Bial-Portela v. Lupin Ltd.*, C.A. No. 18-312-CFC (D. Del.); *Boehringer Ingelheim Pharmaceuticals Inc. et al v. Lupin Limited et al*, C.A. No. 19-01866-CFC (D. Del.).

23. Alternatively, to the extent the above facts do not establish personal jurisdiction over Lupin Ltd., this Court may exercise jurisdiction over Lupin Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Lupin Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Lupin Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Lupin Ltd. satisfies due process.

PERSONAL JURISDICTION OVER LUPIN PHARMA

24. Plaintiffs reallege paragraphs 1-23 as if fully set forth herein.

25. On information and belief, Lupin Pharma develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

26. This Court has personal jurisdiction over Lupin Pharma because, *inter alia*, Lupin Pharma, on information and belief: (1) is incorporated under the laws of the State of Delaware; (2) is registered as a pharmacy wholesaler and controlled substances distributor/manufacturer with the Delaware Division of Professional Regulation; (3) intends to market, sell, or distribute Lupin's ANDA Products to residents of this State; (4) makes its generic drug products available in this State; and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

27. On information and belief, Lupin Pharma has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g.*, *Boehringer Ingelheim Pharm. Inc. v. Lupin Ltd.*, C.A. No. 18-1690-CFC (D. Del.); *Alcon Research, Ltd. v. Lupin Ltd.*, C.A. No. 16-195-GMS-SRF (D. Del.); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Lupin Limited et al.*, C.A. No. 19-1866-CFC (D. Del.).

BACKGROUND

U.S. PATENT NO. 11,090,323

28. On August 17, 2021, the USPTO duly and legally issued United States Patent No. 11,090,323 ("the '323 patent") entitled "Pharmaceutical composition, methods for treating and uses thereof" to inventors Uli Christian Broedl, Sreeraj Macha, Maximilian von Eynatten, and Hans-Juergen Woerle. A true and correct copy of the '323 patent is attached as Exhibit A. The '323 patent is assigned to BII. BIC and BIPI are licensees of the '323 patent.

JARDIANCE®

29. BIPI is the holder of New Drug Application ("NDA") No. 204629 for empagliflozin, for oral use, in 10 mg and 25 mg dosages, which is sold under the trade name JARDIANCE®.

30. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '323 patent is listed in the Orange Book with respect to JARDIANCE®.

31. The '323 patent covers the use of JARDIANCE®.

GLYXAMBI®

32. BIPI is the holder of New Drug Application ("NDA") No. 206073 for empagliflozin/linagliptin, for oral use, in 10 mg/5 mg and 25 mg/5 mg dosages, which is sold under the trade name GLYXAMBI®.

33. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '323 patent is listed in the Orange Book with respect to GLYXAMBI®.

34. The '323 patent covers the GLYXAMBI® product and its use.

SYNJARDY® XR

35. BIPI is the holder of New Drug Application ("NDA") No. 208658 for empagliflozin and metformin hydrochloride, extended release, for oral use, in 5 mg/1 g, 10 mg/1 g, 12.5 mg/1 g, and 25 mg/1 g dosages, which is sold under the trade name SYNJARDY® XR.

36. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '323 patent is among the patents listed in the Orange Book with respect to SYNJARDY® XR.

37. The '323 patent covers the SYNJARDY® XR product and its use.

TRIJARDY® XR

38. BIPI is the holder of New Drug Application ("NDA") No. 212614 for empagliflozin, linagliptin, and metformin hydrochloride, extended release, for oral use, in 5 mg/2.5 mg/1 g, 10 mg/5 mg/1 g, 12.5 mg/2.5 mg/1 g, and 25 mg/5 mg/1 g dosages, which is sold under the trade name TRIJARDY® XR.

39. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '323 patent is among the patents listed in the Orange Book with respect to TRIJARDY® XR.

40. The '323 patent covers the TRIJARDY® XR product and its use.

ACTS GIVING RISE TO THIS ACTION

COUNT I — INFRINGEMENT OF THE '323 PATENT AS TO THE LUPIN EMPAGLIFLOZIN ANDA

41. Plaintiffs reallege paragraphs 1-40 as if fully set forth herein.

42. On information and belief, Lupin submitted the Lupin empagliflozin ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Lupin empagliflozin ANDA Product.

43. Lupin has represented that the Lupin empagliflozin ANDA refers to and relies upon the JARDIANCE® NDA and contains data that, according to Lupin, demonstrate the bioavailability or bioequivalence of the Lupin empagliflozin ANDA Product to JARDIANCE®.

44. Plaintiffs received a letter from Lupin on or about October 4, 2021 (the "Lupin empagliflozin Notice Letter") stating that Lupin had included a certification in the Lupin empagliflozin ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '323 patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Lupin empagliflozin ANDA Product (the "Lupin empagliflozin Paragraph IV Certification"). The Lupin empagliflozin Notice Letter included a detailed statement of the factual and legal bases for Lupin's empagliflozin Paragraph IV Certification (the "Lupin empagliflozin Detailed Statement"). Lupin intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Lupin empagliflozin ANDA Product prior to the expiration of the '323 patent.

45. Lupin has infringed at least one claim of the '323 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted, the Lupin empagliflozin ANDA, by which Lupin seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Lupin empagliflozin ANDA Product prior to the expiration of the '323 patent.

46. Lupin has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Lupin empagliflozin ANDA Product in the event that the FDA approves the Lupin empagliflozin ANDA. Accordingly, an actual and immediate controversy exists regarding Lupin's infringement of the '323 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

47. Lupin's empagliflozin Detailed Statement does not deny that the Lupin empagliflozin ANDA Product subject to ANDA No. 212331 will infringe the claims of the '323 patent.

48. On information and belief, Lupin's use, offer to sell, or sale of the Lupin empagliflozin ANDA Product in the United States during the term of the '323 patent would further infringe at least one claim of the '323 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

49. On information and belief, the Lupin empagliflozin ANDA Product, when offered for sale, sold, and/or when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '323 patent either literally or under the doctrine of equivalents.

50. On information and belief, the use of the Lupin empagliflozin ANDA Product constitutes a material part of at least one of the claims of the '323 patent; Lupin knows that its empagliflozin ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents; and its empagliflozin ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

51. On information and belief, the offering to sell or sale of the Lupin empagliflozin ANDA Product would contributorily infringe at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

52. On information and belief, Lupin had knowledge of the '323 patent and, by its promotional activities and package inserts for its empagliflozin ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

53. On information and belief, the offering to sell or sale of the Lupin empagliflozin ANDA Product by Lupin would actively induce infringement of at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

54. Plaintiffs will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '323 patent.

55. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT II — INFRINGEMENT OF THE '323 PATENT AS TO THE LUPIN EMPAGLIFLOZIN/LINAGLIPTIN ANDA

56. Plaintiffs reallege paragraphs 1-55 as if fully set forth herein.

57. On information and belief, Lupin submitted the Lupin empagliflozin/linagliptin ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Lupin empagliflozin/linagliptin ANDA Product.

58. Lupin has represented that the Lupin empagliflozin/linagliptin ANDA refers to and relies upon the GLYXAMBI® NDA and contains data that, according to Lupin, demonstrate the bioavailability or bioequivalence of the Lupin empagliflozin/linagliptin ANDA Product to GLYXAMBI®.

59. Plaintiffs received a letter from Lupin on or about October 4, 2021 (the "Lupin empagliflozin/linagliptin Notice Letter") stating that Lupin had included a certification in the Lupin empagliflozin/linagliptin ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter*

alia, certain claims of the '323 patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Lupin empagliflozin/linagliptin ANDA Product (the "Lupin empagliflozin/linagliptin Paragraph IV Certification"). The Lupin empagliflozin/linagliptin Notice Letter included a detailed statement of the factual and legal bases for Lupin's empagliflozin/linagliptin Paragraph IV Certification (the "Lupin empagliflozin/linagliptin Detailed Statement"). Lupin intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Lupin empagliflozin/linagliptin ANDA Product prior to the expiration of the '323 patent.

60. Lupin has infringed at least one claim of the '323 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Lupin empagliflozin/linagliptin ANDA, by which Lupin seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Lupin empagliflozin/linagliptin ANDA Product prior to the expiration of the '323 patent.

61. Lupin has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Lupin empagliflozin/linagliptin ANDA Product in the event that the FDA approves the Lupin empagliflozin/linagliptin ANDA. Accordingly, an actual and immediate controversy exists regarding Lupin's infringement of the '323 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

62. Lupin's empagliflozin/linagliptin Detailed Statement does not deny that the Lupin empagliflozin/linagliptin ANDA Product subject to ANDA No. 212335 will infringe the claims of the '323 patent.

63. On information and belief, Lupin's use, offer to sell, or sale of the Lupin empagliflozin/linagliptin ANDA Product in the United States during the term of the '323 patent

would further infringe at least one claim of the '323 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

64. On information and belief, the Lupin empagliflozin/linagliptin ANDA Product, when offered for sale, sold, and/or when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '323 patent either literally or under the doctrine of equivalents.

65. On information and belief, the use of the Lupin empagliflozin/linagliptin ANDA Product constitutes a material part of at least one of the claims of the '323 patent; Lupin knows that its empagliflozin/linagliptin ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents; and its empagliflozin/linagliptin ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

66. On information and belief, the offering to sell or sale of the Lupin empagliflozin/linagliptin ANDA Product would contributorily infringe at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

67. On information and belief, Lupin had knowledge of the '323 patent and, by its promotional activities and package inserts for its empagliflozin/linagliptin ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

68. On information and belief, the offering to sell or sale of the Lupin empagliflozin/linagliptin ANDA Product by Lupin would actively induce infringement of at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

69. Plaintiffs will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '323 patent.

70. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT III — INFRINGEMENT OF THE '323 PATENT AS TO THE LUPIN EMPAGLIFLOZIN/METFORMIN EXTENDED-RELEASE ANDA

71. Plaintiffs reallege paragraphs 1-70 as if fully set forth herein.

72. On information and belief, Lupin submitted the Lupin empagliflozin/metformin extended-release ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Lupin empagliflozin/metformin extended-release ANDA Product.

73. Lupin has represented that the Lupin empagliflozin/metformin extended-release ANDA refers to and relies upon the SYNJARDY® XR NDA and contains data that, according to Lupin, demonstrate the bioavailability or bioequivalence of the Lupin empagliflozin/metformin extended-release ANDA Product to SYNJARDY® XR.

74. Plaintiffs received a letter from Lupin on or about October 4, 2021 (the "Lupin empagliflozin/metformin extended-release Notice Letter") stating that Lupin had included a certification in the Lupin empagliflozin/metformin extended-release ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '323 patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Lupin empagliflozin/metformin extended-release ANDA Product (the "Lupin empagliflozin/metformin extended-release Paragraph IV Certification"). The Lupin empagliflozin/metformin extended-release Notice Letter included a detailed statement of the factual and legal bases for Lupin's empagliflozin/metformin extended-release Paragraph IV Certification (the "Lupin empagliflozin/metformin extended-release Detailed Statement"). Lupin intends to engage in the commercial manufacture, use, offer

for sale, and/or sale of the Lupin empagliflozin/metformin extended-release ANDA Product prior to the expiration of the '323 patent.

75. Lupin has infringed at least one claim of the '323 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Lupin empagliflozin/metformin extended-release ANDA, by which Lupin seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Lupin empagliflozin/metformin extended-release ANDA Product prior to the expiration of the '323 patent.

76. Lupin has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Lupin empagliflozin/metformin extended-release ANDA Product in the event that the FDA approves the Lupin empagliflozin/metformin extended-release ANDA. Accordingly, an actual and immediate controversy exists regarding Lupin's infringement of the '323 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

77. Lupin's empagliflozin/metformin extended-release Detailed Statement does not deny that the Lupin empagliflozin/metformin extended-release ANDA Product subject to ANDA No. 213654 will infringe the claims of the '323 patent.

78. On information and belief, Lupin's use, offer to sell, or sale of the Lupin empagliflozin/metformin extended-release ANDA Product in the United States during the term of the '323 patent would further infringe at least one claim of the '323 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

79. On information and belief, the Lupin empagliflozin/metformin extended-release ANDA Product, when offered for sale, sold, and/or when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '323 patent either literally or under the doctrine of equivalents.

80. On information and belief, the use of the Lupin empagliflozin/metformin extended-release ANDA Product constitutes a material part of at least one of the claims of the '323 patent; Lupin knows that its empagliflozin/metformin extended-release ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents; and its empagliflozin/metformin extended-release ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

81. On information and belief, the offering to sell or sale of the Lupin empagliflozin/metformin extended-release ANDA Product would contributorily infringe at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

82. On information and belief, Lupin had knowledge of the '323 patent and, by its promotional activities and package inserts for its empagliflozin/metformin extended-release ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

83. On information and belief, the offering to sell or sale of the Lupin empagliflozin/metformin extended-release ANDA Product by Lupin would actively induce infringement of at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

84. Plaintiffs will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '323 patent.

85. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT IV — INFRINGEMENT OF THE '323 PATENT AS TO THE LUPIN EMPAGLIFLOZIN/LINAGLIPTIN/METFORMIN EXTENDED-RELEASE ANDA

86. Plaintiffs reallege paragraphs 1-85 as if fully set forth herein.

87. On information and belief, Lupin submitted the Lupin empagliflozin/linagliptin/metformin extended-release ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Lupin empagliflozin/linagliptin/metformin extended-release ANDA Product.

88. Lupin has represented that the Lupin empagliflozin/linagliptin/metformin extended-release ANDA refers to and relies upon the TRIJARDY® XR NDA and contains data that, according to Lupin, demonstrate the bioavailability or bioequivalence of the Lupin empagliflozin/linagliptin/metformin extended-release ANDA Product to TRIJARDY® XR.

89. Plaintiffs received a letter from Lupin on or about October 4, 2021 (the "Lupin empagliflozin/linagliptin/metformin extended-release Notice Letter") stating that Lupin had included a certification in the Lupin empagliflozin/linagliptin/metformin extended-release ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '323 patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Lupin empagliflozin/linagliptin/metformin extended-release ANDA Product (the "Lupin empagliflozin/linagliptin/metformin extended-release Paragraph IV Certification"). The Lupin empagliflozin/linagliptin/metformin extended-release Notice Letter included a detailed statement of the factual and legal bases for Lupin's empagliflozin/linagliptin/metformin extended-release Paragraph IV Certification (the "Lupin empagliflozin/linagliptin/metformin extended-release Detailed Statement"). Lupin intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Lupin empagliflozin/linagliptin/metformin extended-release ANDA Product prior to the expiration of the '323 patent.

90. Lupin has infringed at least one claim of the '323 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Lupin empagliflozin/linagliptin/metformin extended-release ANDA, by which Lupin seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Lupin empagliflozin/linagliptin/metformin extended-release ANDA Product prior to the expiration of the '323 patent.

91. Lupin has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Lupin empagliflozin/linagliptin/metformin extended-release ANDA Product in the event that the FDA approves the Lupin empagliflozin/linagliptin/metformin extended-release ANDA. Accordingly, an actual and immediate controversy exists regarding Lupin's infringement of the '323 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

92. Lupin's empagliflozin/linagliptin/metformin extended-release Detailed Statement does not deny that the Lupin empagliflozin/linagliptin/metformin extended-release ANDA Product subject to ANDA No. 215072 will infringe the claims of the '323 patent.

93. On information and belief, Lupin's use, offer to sell, or sale of the Lupin empagliflozin/linagliptin/metformin extended-release ANDA Product in the United States during the term of the '323 patent would further infringe at least one claim of the '323 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

94. On information and belief, the Lupin empagliflozin/linagliptin/metformin extended-release ANDA Product, when offered for sale, sold, and/or when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '323 patent either literally or under the doctrine of equivalents.

95. On information and belief, the use of the Lupin empagliflozin/linagliptin/metformin extended-release ANDA Product constitutes a material part of at least one of the claims of the '323 patent; Lupin knows that its empagliflozin/linagliptin/metformin extended-release ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents; and its empagliflozin/linagliptin/metformin extended-release ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

96. On information and belief, the offering to sell or sale of the Lupin empagliflozin/linagliptin/metformin extended-release ANDA Product would contributorily infringe at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

97. On information and belief, Lupin had knowledge of the '323 patent and, by its promotional activities and package inserts for its empagliflozin/linagliptin/metformin extended-release ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

98. On information and belief, the offering to sell or sale of the Lupin empagliflozin/linagliptin/metformin extended-release ANDA Product by Lupin would actively induce infringement of at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

99. Plaintiffs will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '323 patent.

100. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Lupin and for the following relief:

a. A Judgment be entered that Lupin has infringed at least one claim of the '323 patent by submitting the Lupin empagliflozin ANDA;

b. A Judgment be entered that Lupin has infringed at least one claim of the '323 patent by submitting the Lupin empagliflozin/linagliptin ANDA;

c. A Judgment be entered that Lupin has infringed at least one claim of the '323 patent by submitting the Lupin empagliflozin/metformin extended-release ANDA;

d. A Judgment be entered that Lupin has infringed at least one claim of the '323 patent by submitting the Lupin empagliflozin/linagliptin/metformin extended-release ANDA;

e. That Lupin, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them be preliminarily and permanently enjoined from: (i) engaging in the commercial use, offer to sell, or sale within the United States of drugs or methods of administering drugs claimed in the '323 patent, and (ii) seeking, obtaining or maintaining approval of Lupin's empagliflozin ANDA until the expiration of the '323 patent or such other later time as the Court may determine;

f. That Lupin, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them be preliminarily and permanently enjoined from: (i) engaging in the commercial use, offer to sell, or sale

within the United States of drugs or methods of administering drugs claimed in the '323 patent, and (ii) seeking, obtaining or maintaining approval of Lupin's empagliflozin/linagliptin ANDA until the expiration of the '323 patent or such other later time as the Court may determine;

g. That Lupin, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them be preliminarily and permanently enjoined from: (i) engaging in the commercial use, offer to sell, or sale within the United States of drugs or methods of administering drugs claimed in the '323 patent, and (ii) seeking, obtaining or maintaining approval of Lupin's empagliflozin/metformin extended-release ANDA until the expiration of the '323 patent or such other later time as the Court may determine;

h. That Lupin, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them be preliminarily and permanently enjoined from: (i) engaging in the commercial use, offer to sell, or sale within the United States of drugs or methods of administering drugs claimed in the '323 patent, and (ii) seeking, obtaining or maintaining approval of Lupin's empagliflozin/linagliptin/metformin extended-release ANDA until the expiration of the '323 patent or such other later time as the Court may determine;

i. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Lupin's empagliflozin ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration date of the '323 patent, including any extensions;

j. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Lupin's empagliflozin/linagliptin ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration date of the '323 patent, including any extensions;

k. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Lupin's empagliflozin/metformin extended-release ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration date of the '323 patent, including any extensions;

l. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Lupin's empagliflozin/linagliptin/metformin extended-release ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration date of the '323 patent, including any extensions;

m. That Boehringer be awarded monetary relief if Lupin commercially uses, offers to sell, or sells its respective proposed generic version of JARDIANCE® or any other product that infringes or induces or contributes to the infringement of the '323 patent, within the United States, prior to the expiration of this patent, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

n. That Boehringer be awarded monetary relief if Lupin commercially uses, offers to sell, or sells its respective proposed generic version of GLYXAMBI® or any other product that infringes or induces or contributes to the infringement of the '323

patent, within the United States, prior to the expiration of this patent, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

o. That Boehringer be awarded monetary relief if Lupin commercially uses, offers to sell, or sells its respective proposed generic version of SYNJARDY® XR or any other product that infringes or induces or contributes to the infringement of the '323 patent, within the United States, prior to the expiration of this patent, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

p. That Boehringer be awarded monetary relief if Lupin commercially uses, offers to sell, or sells its respective proposed generic version of TRIJARDY® XR or any other product that infringes or induces or contributes to the infringement of the '323 patent, within the United States, prior to the expiration of this patent, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

q. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

r. Costs and expenses in this action; and

s. Such other and further relief as the Court deems just and appropriate.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

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